Arcutis Announces Publication of Positive Data from INTEGUMENT-PED Trial Evaluating ZORYVE® (roflumilast) Cream 0.05% in Children 2 to 5 Years Old with Mild to Moderate Atopic Dermatitis in Pediatric Dermatology

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- ZORYVE® (roflumilast) cream 0.05% improved atopic dermatitis (AD) across all primary and secondary efficacy endpoints, with significant improvement as early as Week 1 on multiple efficacy endpoints.
- 39.4% of children treated with roflumilast cream 0.05% achieved a 75% improvement in Eczema Area and Severity Index (EASI-75), a key secondary endpoint.
- Children treated with ZORYVE cream experienced improvement in itch as early as 24 hours.
- Efficacy and safety results were consistent with previous trials of ZORYVE cream 0.15% in adults and children with AD down to age 6.
- Approximately 1.8 million children with atopic dermatitis (AD) aged 2 to 5 are topically treated in the United States.
- Supplemental New Drug Application (sNDA) for ZORYVE cream 0.05% submitted to the U.S. Food and Drug Administration (FDA).

WESTLAKE VILLAGE, Calif., Feb. 24, 2025 (GLOBE NEWSWIRE) -- Arcutis Biotherapeutics, Inc. (Nasdaq: ARQT), a commercial-stage biopharmaceutical company focused on developing meaningful innovations in immuno-dermatology, today announced that *Pediatric Dermatology* published online positive results from INTEGUMENT-PED, the pivotal phase 3 randomized vehicle-controlled trial evaluating the efficacy and safety of ZORYVE (roflumilast) cream 0.05% as a once-daily, steroid-free treatment for mild to moderate atopic dermatitis (AD) in children 2 to 5 years old.

The study found that treatment with investigational once-daily ZORYVE cream 0.05% resulted in significant improvements across multiple efficacy endpoints, including achieving a statistically significant improvement in the primary efficacy endpoint of IGA Success, as well as statistically significant improvements in additional endpoints, including 75% improvement in the Eczema Area and Severity Index (EASI-75) and Worst Itch Numeric Scale (WI-NRS) at Week 4. The data also show improvement in itch (pruritus) was observed as early as 24 hours after first application.

“AD is a chronic, inflammatory skin disease affecting 1.8 million children ages 2 to 5 in the United States with burdensome symptoms that often result in impaired quality of life for both patients and their caregivers,” said Lawrence F. Eichenfield, MD, chief of pediatric and adolescent dermatology at Rady Children's Hospital-San Diego and lead author on the publication. “Results from the INTEGUMENT-PED trial demonstrate that ZORYVE cream 0.05% can quickly and reliably improve the symptoms of AD, especially itch. The publication of these results and the entire clinical development program highlight that ZORYVE cream 0.05%, if approved, could fill a significant gap in the current treatment landscape for a once-daily steroid-free topical therapy that is appropriate for both the short and long-term management of AD, key concerns for young patients and their caregivers.”

INTEGUMENT-PED is a Phase 3, parallel group, double blind, vehicle-controlled trial in which roflumilast cream 0.05% or vehicle was applied once daily for four weeks to children 2 to 5 years of age with mild to moderate AD. A total of 652 children were enrolled in the study, with a mean Body Surface Area (BSA) of 22% overall, and a range from 3% to 82%.

As previously reported, at Week 4, 25.4% of children treated with ZORYVE cream 0.05% achieved vIGA-AD Success, defined as a validated Investigator Global Assessment – Atopic Dermatitis (vIGA-AD) score of ‘Clear’ or ‘Almost Clear’ plus a 2-grade improvement from baseline, compared to 10.7% of children treated with vehicle (P<0.0001), with significant improvements seen as early as Week 1. Other key findings included:

- Rapid improvement in itch was observed in children treated with ZORYVE cream within 24 hours of the first application, as measured by the change from baseline in daily WI-NRS scores, compared with vehicle (nominal P≤.0014).
- 35.3% of children treated with ZORYVE cream achieved a four-point reduction in WI-NRS at Week 4 vs. 18.0% for vehicle-treated subjects (nominal P=0.0002).
- 39.4% of children treated with ZORYVE cream achieved a 75% improvement in EASI score (EASI-75) at Week 4 compared to 20.6% treated with vehicle (P<0.0001). Significant improvements based on EASI-75 were observed with ZORYVE cream compared to vehicle as early as Week 1.
- 35.4% of children treated with ZORYVE cream 0.05% achieved a vIGA-AD score of ‘clear’ or ‘almost clear’ at Week 4, with significant improvements seen as early as Week 1.
- ZORYVE cream was very well-tolerated. The incidence of Treatment Emergent Adverse Events (TEAEs) was low and similar in both active treatment and vehicle arms. The most frequent adverse events in the ZORYVE cream arm (≥2%) included upper respiratory tract infection, diarrhea, and vomiting. All individual AEs occurred in <4.1% of patients.
- Safety and tolerability results were consistent with previous trials of ZORYVE cream 0.15% in patients aged ≥6 years with AD.

“On the heels of our recent submission of a sNDA to the FDA for ZORYVE cream 0.05%, we’re proud to share the full INTEGUMENT-PED results published in *Pediatric Dermatology* with the dermatology community, supporting the well-established efficacy, safety, and tolerability profile of this lower concentration of ZORYVE cream,” said Patrick Burnett, MD, PhD, FAAD, chief medical officer at Arcutis. “We’re committed to bringing forth meaningful innovation and addressing the significant unmet need for topical treatments of young children living with the challenges of AD. We look

forward to the FDA's potential approval of ZORYVE cream 0.05% anticipated later this year."

About ZORYVE (roflumilast) Cream
Roflumilast cream is a next generation topical PDE4 inhibitor. PDE4 – an established target in dermatology – is an intracellular enzyme that increases the production of pro-inflammatory mediators and decreases production of anti-inflammatory mediators. Roflumilast cream 0.3% (ZORYVE®) is approved by the FDA for the topical treatment of plaque psoriasis, including intertriginous areas, in patients 6 years of age and older. Roflumilast cream 0.15% (ZORYVE®) is approved by the FDA for the topical treatment of mild to moderate AD in patients 6 years of age and older. In 2024, ZORYVE cream 0.15% was awarded Glamour's Beauty and Wellness award for "Eczema Product."

INDICATIONS
ZORYVE cream, 0.3%, is indicated for topical treatment of plaque psoriasis, including intertriginous areas, in adult and pediatric patients 6 years of age and older.

ZORYVE cream, 0.15%, is indicated for topical treatment of mild to moderate atopic dermatitis in adult and pediatric patients 6 years of age and older.

IMPORTANT SAFETY INFORMATION
ZORYVE is contraindicated in patients with moderate to severe liver impairment (Child-Pugh B or C).

The most common adverse reactions (≥1%) for ZORYVE cream 0.3% for plaque psoriasis include diarrhea (3.1%), headache (2.4%), insomnia (1.4%), nausea (1.2%), application site pain (1.0%), upper respiratory tract infection (1.0%), and urinary tract infection (1.0%).

The most common adverse reactions (≥1%) for ZORYVE cream 0.15% for atopic dermatitis include headache (2.9%), nausea (1.9%), application site pain (1.5%), diarrhea (1.5%), and vomiting (1.5%).

Please see full Prescribing Information.

About Arcutis
Arcutis Biotherapeutics, Inc. (Nasdaq: ARQT) is a commercial-stage medical dermatology company that champions meaningful innovation to address the urgent needs of individuals living with immune-mediated dermatological diseases and conditions. With a commitment to solving the most persistent patient challenges in dermatology, Arcutis has a growing portfolio including three FDA approved products that harness our unique dermatology development platform coupled with our dermatology expertise to build differentiated therapies against biologically validated targets. Arcutis' dermatology development platform includes a robust pipeline with multiple clinical programs for a range of inflammatory dermatological conditions including scalp and body psoriasis, AD, and alopecia areata. For more information, visit www.arcutis.com or follow Arcutis on LinkedIn, Facebook, Instagram, and X.

Forward-Looking Statements
Arcutis cautions you that statements contained in this press release regarding matters that are not historical facts are forward-looking statements. These statements are based on the Company's current beliefs and expectations. Such forward-looking statements include, but are not limited to, statements regarding the potential FDA approval of ZORYVE cream 0.05%, the potential of real-world use results of ZORYVE cream in AD in children aged 2 to 5, and the potential for ZORYVE cream to advance the standard of care in AD and other inflammatory dermatological conditions. These statements are subject to substantial known and unknown risks, uncertainties and other factors that may cause our actual results, levels of activity, performance, or achievements to be materially different from the information expressed or implied by these forward-looking statements. Risks and uncertainties that may cause our actual results to differ include risks inherent in our business, reimbursement and access to our products, the impact of competition and other important factors discussed in the "Risk Factors" section of our Form 10-K filed with the U.S. Securities and Exchange Commission (SEC) on February 27, 2024, as well as any subsequent filings with the SEC. You should not place undue reliance on any forward-looking statements in this press release. We undertake no obligation to revise or update information herein to reflect events or circumstances in the future, even if new information becomes available. All forward-looking statements are qualified in their entirety by this cautionary statement, which is made under the safe harbor provisions of the Private Securities Litigation Reform Act of 1995.

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